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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/681,827	10/07/2003	Bishwajit Nag	BEX1P004	6590

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EXAMINER	
CORDERO GARCIA, MARCELA M	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 10/21/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/681,827	NAG ET AL.	
	Examiner	Art Unit	
	Marcela M. Cordero Garcia	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 August 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,8,9,15-21,25 and 26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,8,9,15-21,25 and 26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

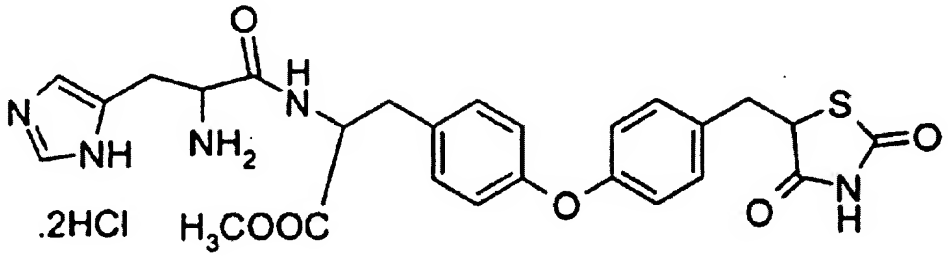
Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Acknowledgment is made of the reply and terminal disclaimer received on August 10, 2005.

Claims 1-4, 6, 8, 9, 15-21, 25 and 26 are pending in the application, in so far as they read on the elected species:



Claims 1-4, 6, 8, 9, 15-21, 25 and 26 are presented for examination on the merits as they read upon the above species.

Any objection or rejection from the previous office action, which is not restated here, is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-4, 6, 8, 9, 15-21, 25 and 26 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered vague and indefinite by the phrase in line 4: "their derivatives, their analogs" because it is unclear what structurally constitutes a derivative and/or an analog of a formula I compound, and therefore the terms fail to define the metes and bounds of the invention

Claim 1 is also rendered vague and indefinite by the phrase in line 16: "an amino acid or a derivative thereof" because it is unclear what structurally constitutes a derivative of an amino acid is and therefore the claim fails to define the metes and bounds of the invention.

Claim 3 is rendered vague and indefinite by the phrase in line 4: "or their derivatives" for the reasons set forth above.

Claims 6-8 are rendered vague and indefinite by the phrase in lines 1-2: "or a derivative thereof" for the reasons set forth above.

Claims 16-21 are rendered vague and indefinite by the phrase "their derivatives, their analogs" in line 4, and by the phrase "a derivative thereof" in line 15, for the reasons set forth above.

All other claims that depend directly or indirectly from rejected claims and are, therefore, also stand rejected under USC 112, second paragraph for the reasons set forth above.

Applicant traverses the rejection on the grounds that the definitions of the terms "analogs" and "derivative" are set forth on page 12 of the specification and thus Applicant submits that the claims comply with 35 U.S.C. 112, second paragraph.

At lines 10-11 of page 12, the specification reads:
"The term "analogs" refers to a set of compounds which differ from one another only by replacement of one or more heteroatoms, such as O, S, or N, with a different heteroatom." In addition, at lines 18-20 of page 12, the specification reads:
"The term "derivative" refers to a compound obtained from another compound by a simple chemical process; e.g., acetic acid is a derivative of ethanol by oxidation; N-acetyl ethylamine is a derivative of ethylamine by acetylation."

Examiner has carefully considered the arguments, but has not deemed them to be persuasive because, the aforementioned 'definitions' of page 12 do not disclose unique definitions per se and therefore the instant terms are not limited to the pertaining subject matter assigned thereof in the specification, but are instead broader, i.e., the term "refers to" does not limit to the indicated subject matter in the provided citations, since it does not firmly delineates the boundaries as when using, e.g., "is defined as...", "is..." or "means...". As drafted in the specification, other definitions accepted in the art may also be used for these terms, such as "Derivative is a compound derived or obtained from another and containing essential elements of the parent substance" (Accesed online 10/18/2005 at http://www.answers.com/derivative) and "The term analog is a structural derivative of a parent compound that often differs from it by a single element." (Accessed online 10/18/2005 at http://www.answers.com/analog).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-4, 6, 8, 9, 15, 16, 18, 19, 20, 21, 25 and 26 stand rejected under 35 U.S.C. 102(e) as being anticipated by Nag et al. (US 6,794,401, reference A16 in IDS of October 5, 2004).

Nag et al. teach derivatives or analogs of the dipeptide phenyl ethers and/or processes of preparation of the instantly claimed formula (I). (See, e.g., column 51, Example I).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

Applicant traverses this rejection on the grounds that the cited compound in column 51, Example 1 of the reference has a substituent on the left side of the formula that occurs on the phenyl ring. To the far left of that formula, the substituent does not come within the definition of the substituent C_2-C_1-B-A- in the present Formula I. In particular, in Formula I, C_2 and C_1 are both amino acids. In the formula cited in column 51 there is only a single amino acid present. Therefore the claim 51 does not anticipate the present claims and there are no other compounds disclosed in Nag et al. which come within the formula defined in Formula I of the present application.

Applicant's arguments have been carefully considered, but not deemed persuasive because, as indicated in the 35 U.S.C. 112, second paragraph rejection above, the term "derivatives thereof" encompasses compounds derived or obtained from another and containing essential elements of the parent substance (See, e.g., http://www.answers.com/derivative), and therefore the compound taught by Nag et al. reads upon the instantly claimed invention since the compound of column 51, Example 1 encompasses a compound derived or obtained from another and containing essential elements of the parent substance (i.e., the parent substance in this case is the species instantly examined, from which the reference compound differs only on the leftmost part of the molecule, as readily admitted by Applicant).

Claims 1-4, 6, 8, 9, 25 and 26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Fujita et al. (US 6,562,849).

Fujita et al. teach derivatives or analogs of the dipeptide phenyl ethers of the instantly claimed formula (I). (See, e.g., columns 65, 66, 77 and 78).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

Applicant traverses this rejection on the grounds that the cited compounds in columns 65-66 and 77-78 of the reference have a substituent on the left side of the formula from the phenyl ring, which do not fall within the definition of the substituent C_2-C_1-B-A- in the present Formula I. In particular, in Formula I, C_2 and C_1 are both amino acids joined together by an amide bond. No such moiety exists in the substituents of the phenyl ring in Fujita et al. Accordingly, Applicant submits that this reference does not anticipate the present claims.

Applicant's arguments have been carefully considered, but not deemed persuasive because, as indicated in the 35 U.S.C. 112, second paragraph rejection above, the term "derivatives thereof" encompasses compounds derived or obtained from another and containing essential elements of the parent substance (See, e.g., http://www.answers.com/derivative), and therefore the compounds taught by Fujita et al. reads upon the instantly claimed invention since the compounds of columns 65-66 and 77-78 encompass compounds derived or obtained from another and containing essential elements of the parent substance (i.e., the parent substance is in this case the

species instantly examined, from which the reference compounds differ on the leftmost part of the molecule, as readily admitted by Applicant).

Claims 1-4, 6, 8, 9, 25 and 26 stand rejected under 35 U.S.C. 102(b) as being anticipated by Sohda et al. (US 6,552,058, reference A7 in IDS of October 5, 2004).

Sohda et al. teach derivatives or analogs of the dipeptide phenyl ethers of the instantly claimed formula (I). (See, e.g., columns 1-4).

Therefore, the reference is deemed to anticipate the instant claims above, as drafted.

Applicant traverses the rejection because in the formulas of columns 1-4 of the reference the left hand substituent on the phenyl ring is described as $R\text{-}(Y)_m\text{-}(CH_2)_n\text{-}CHR^1\text{-}O\text{-}$. In Sohda et al. the component Y can be a -CO- or NR_3, which means there can be only a carbonyl or an amine in the entire substituent. Therefore, the substituent described above in Sohda et al. does not fall within the scope of $C_2\text{-}C_1\text{-}B\text{-}A\text{-}$ in the Formula I of the present application.

Applicant's arguments have been carefully considered, but not deemed persuasive because, as indicated in the 35 U.S.C. 112, second paragraph rejection above, the term "derivatives thereof" encompasses compounds derived or obtained from another and containing essential elements of the parent substance (See, e.g., http://www.answers.com/derivative), and therefore the compound taught by Sohda et al. reads upon the instantly claimed invention since the compounds of columns 1-4, encompass compounds derived or obtained from another and containing essential

elements of the parent substance (i.e., the parent substance is in this case the species instantly examined, from which the reference compound differs only on the leftmost part of the molecule, as readily admitted by Applicant).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 8, 9, 15, 16, 17, 18, 19, 20, 21, 25 and 26 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Nag et al. (US 6,794,401).

Nag et al. (US 6,794,401) teach derivatives or analogs and/or processes of preparation of the instantly claimed dipeptide phenyl ethers of formula (I). [See, e.g., column 51, Example I and claims].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust particular conventional working conditions within such synthetic method (e.g., using different paths / protecting groups in order to optimize the yield) based upon the overall beneficial teachings provided by Nag et al. These types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

Thus, the invention as a whole is prima facie obvious over the reference, especially in the absence of evidence to the contrary.

Applicant's traversal of the rejection is on the grounds that Nag et al. do not teach analogs of the compounds according to the present Formula I. According to the common chemical definition of "analogs" which is consistent with Applicant's definition set forth on page 12 of the present application, an analog is one in which two compounds differ only by replacement by one or more heteroatoms. The compounds of Formula I contain at least an additional amino acid, C_1, which is not obtained by merely replacing one or more heteroatoms into formulas described by Nag et al., the presently claimed compounds are not analogs of those disclosed in Nag et al. Neither are the compound derivatives of those described in Nag et al. As discussed on page 12 of the present specification, a derivative refers to a compound obtained from another compound by simple chemical process, such as by an oxidation or an acylation. However, one cannot obtain the class of compounds of the present Formula I by a simple chemical process from the single amino acid containing compounds in Nag et al. Not only is there a possibility of interference from other functionalities in substituents R_1,

R_2, R_3 and R_4 in Nag et al.'s Formula I (see claim 1 of Nag et al.'s), but the possible side chains on X itself are possible interfering functionalities. Therefore, it is submitted that the class of compounds of Applicant's Formula I are not derivatives of Nag et al.'s compounds of the Formula I. Applicant also argues that the examiner fails to cite the motivation for making compounds according to the instantly claimed Formula I. Among the many possible ways to modify the compounds of Formula I in Nag et al. Applicant would like to be provided with the specific quote that one should only modify at the site of the moiety X and would like to know where is the motivation that the site at X should be modified only by adding an alpha amino acid. There is no teaching in Nag et al. to motivate one of ordinary skill in the art to make such modifications. Accordingly, it is submitted that the present claims are unobvious over Nag et al.

Applicant's arguments have been carefully considered, but not deemed persuasive because, as indicated in the 35 U.S.C. 112, second paragraph rejection above, the term "derivatives thereof" encompasses compounds derived or obtained from another and containing essential elements of the parent substance (See, e.g., http://www.answers.com/derivative), and therefore the compound taught by Nag et al. reads upon the instantly claimed invention since the compound of column 51, Example 1 encompasses a compound derived or obtained from another and containing essential elements of the parent substance (i.e., the parent substance in this case is the species instantly examined, from which the reference compound differs only on the leftmost part of the molecule, as readily admitted by Applicant). The different methods of making of the instantly claimed compounds, as it is of record from the previous Office Action,

would have been obvious to one of ordinary skill in the art at the time the invention was made, by adjusting particular conventional working conditions within the synthetic method of Nag et al. (e.g., using different paths / protecting groups in order to optimize the yield) based upon the overall beneficial teachings provided by Nag et al (See, e.g., Example 1). It is restated therefore that these types of adjustments are deemed merely a matter of judicious selection and routine optimization that is well within the purview of the skilled artisan.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

No claim is allowed.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marcela M Cordero Garcia whose telephone number is (571) 272-2939. The examiner can normally be reached on M-Th 7:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Patent Examiner
Art Unit 1654

MMCG 03/05

CHRISTOPHER R. TATE
PRIMARY EXAMINER